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ENDOCARDIAL SOLUTIONS

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JUN - 7 2000

510(k) Summary

Submitter: Endocardial Solutions
1350 Energy Lane, Suite 110
St. Paul, MN 55108 USA
Phone: 651-523-6900
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Contact: James W. Bullock
President and CEO

Date Prepared: May 5, 2000

Trade Name: EnSite 3000® System

a) Model EC 1000 EnSite® Multi-electrode Diagnostic Catheter
b) EnSite 3000® Electrophysiology Workstation

Common name: Electrophysiology cardiac mapping system

Classification Name: a) Electrode recording catheter or electrode recording probe (21CFR 870.1220)

b) Programmable diagnostic computer (21 CFR 870.1425)

Predicate Device: Endocardial Solutions EnSite 3000 System
510(k) No. K992479

Device Description:

The EnSite 3000 System is a computerized storage and display system for use in electrophysiology studies of the human heart. The system consists of a console workstation, patient interface unit, and an electrophysiology mapping catheter.

Unlike currently available electrode recording catheters, the EnSite Catheter does not require direct contact with the endocardium for the detection of intracardiac electrograms. The EnSite 3000 Electrophysiology Workstation connected to the EnSite Catheter utilizes proprietary software algorithms to reconstruct and display right atrial electrograms detected by the EnSite Catheter. This information can be presented as color-coded three-dimensional maps to provide global electrical activation patterns of the heart

chamber. The EnSite 3000 System may also be used in conjunction with standard electrode mapping catheters, programmable cardiac stimulators, ECG leads, and other analog or digital inputs.

The EnSite 3000 System also incorporates a navigational tool to provide real-time feedback regarding the position of an auxiliary catheter for creation of a geometrical model of the heart chamber or for guiding therapy to a designated location.

Intended use:

The EnSite Multi-electrode Diagnostic Catheter used with the EnSite 3000 Electrophysiology Workstation is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters).

Technological Characteristics:

The new device has the same technological characteristics as the legally marketed predicate device.

Non-clinical performance data:

The changes made to the EnSite 3000 System underwent a battery of bench and user tests. Device validation testing was conducted in accordance with in-house procedures.

Conclusion:

An evaluation of the device changes indicates that the device is as safe and effective as the previously marketed device to which it is being compared and does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2000

Mr. James W. Bullock
President and Chief Executive Officer
Endocardial Solutions
1350 Energy Lane
Suite 110
Saint Paul, MN 55108-5254

Re: K001437
EnSite 3000 System
Regulatory Class: II (two)
Product Code: DQK
Dated: May 5, 2000
Received: May 8, 2000

Dear Mr. Bullock:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office for Device Evaluation
Center for Devices and Radiological
Health

Enclosure

510(k) Number (if known):

Device Name: EnSite® 3000 System

Indications for Use:

The EnSite® Multi-electrode Diagnostic Catheter used with the EnSite 3000® Electrophysiology Workstation is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional format 3-10-98)

for Mark N Milleresen

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001437